REMARKS

I. Amendments to the Specification

In the specification, a new paragraph has been added after line 6 of page 9. This amendment does not add any new matter.

The paragraphs at: (a) page 7, line 18 to page 8, line 9; (b) page 31, lines 10-24; (c) page 32, lines 9-21; and (d) page 35, line 23 to page 36, line 11 have been amended to correct editorial problems, obvious errors (*see,* MPEP § 2163.07 at Section II) and/or to account for the amendment of FIG. 13 (see below). No new matter has been added by these amendments.

The paragraph at page 35, line 7-14 has been amended to account for the amendment of FIG. 13 (i.e., the addition of previously omitted element numerals 600, 602, 604 and 606) and also to make it clear that when pressure relief valves 391, 392, and 394 open, the fluid from each of these valves flows to a reject outlet via a reject line 600. Support for this amendment can be found in FIG. 13 which shows that the fluids coming from pressure relief valves 391, 392, and 394 flow into a line (element numeral 600 in amended FIG. 13). Further, FIG. 13 shows that line 600 goes to the reject outlet. Hence, line 600 is a "reject line". No new matter has been added by this amendment. See, MPEP 608.04 ("In establishing a disclosure, applicant may rely not only on the specification and drawing as filed....") (underscoring added). See also, MPEP § 2163 at II.A.3,(a), citing, *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 ("drawings alone may provide a 'written description' of an invention as required by Sec. 112...."); *Autogiro Co. of America v. United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same

manner and with the same limitations as the specification."); and *In re Wolfensperger*, 133 USPQ 537, 542 (CCPA 1962) ("The practical legitimate enquiry in each case of this kind is what the drawing in fact discloses to one skilled in the art. Whatever it does disclose may be added to the specification in words without violation of the statute and rule which prohibit new matter...for the simple reason *that* what *is* originally disclosed cannot be 'new matter' within the meaning of this law.")

The paragraph at page 35, line 15-22 has been amended to correct an obvious error, i.e., that the product fluid from the heat exchanger 416 passes through a third filter 374, not 372. This paragraph has also been amended to make it clear that as the product fluid exits the heat exchanger 416, the product fluid passes through the third filter 374 and a second flow restrictor 398 via a product line 602. Support for these amendments can be found in FIG. 13, which shows that from the heat exchanger, the product fluid flows into the third filter 374 and second flow restrictor 398 through a line (element numeral 602 in amended FIG. 13). Further, FIG. 13 shows that line 602 leads to the product outlet. Hence, line 602 is a "product line". No new matter has been added by this amendment. See above: MPEP 608.04; *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118; *Autogiro*, 384 F.2d 391, 398, 155 USPQ 697, 703; and *In re Wolfensperger*, 133 USPQ 537, 542 (CCPA 1962). See also, specification, at page 36, line 15 *et seq.*

The paragraph at page 35, line 15-22 has also been amended to make it clear that a portion of the product fluid from the second flow restrictor 398 is diverted from the product line via a sampling line 604 to pass through an endotoxin sensor 410'. Support for this amendment can be found in FIG. 13 which shows a line (element numeral 604 in amended FIG. 13) leading away from product line 602 and going towards reject line 600. It is clear from FIG. 13 that line

604 diverts a portion of the product fluid flowing from the second flow restrictor so as to pass through endotoxin sensor 410' disposed along line 604. Since line 604 diverts a portion of the product fluid so that the endotoxin level of product fluid can be measured, line 604 is a "sampling line". No new matter has been added by this amendment. See above: MPEP 608.04; *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118; *Autogiro*, 384 F.2d 391, 398, 155 USPQ 697, 703; and *In re Wolfensperger*, 133 USPQ at 542 (CCPA 1962).

II. Amendments to the Drawings

In amended FIG. 13, previously omitted element numerals 600, 602, 604 and 606 have been added. No new matter has been added by these amendments.

III. Amendments to the Claims

Claim 1-72 remains in this application. Claims 1, 20, 21, 30, 54, 60, 63, 65, 66, 69 and 70 have been amended. New claim 73 has been added.

Claim 1 has been amended to correct an obvious error by replacing the word "control" on page 39, line 14 with the word "relief".

Claim 20 has been amended by replacing the word "product" with "discharge". Support for this amendment can be found in the specification at page 36, lines 15 *et seq.*

Claim 21 has been amended by replacing the word "endotoxin" with "flow" and replacing the word "discharge" with "divert". Support for this amendment can be found in the specification at page 35, line 23 *et seq.* and FIG. 13.

Claims 30, 54, 60, 63, 65, 66, and 69 have been amended to correct errors in punctuation and/or grammar.

Claim 70 has been amended to correct an obvious numbering error by replacing "68" with "69".

New claim 73 has been added. Support for this new claim can be found in the specification at page 35, line 15 *et seq.*, as amended. ("A portion of the product fluid from the second flow restrictor is diverted via a sampling line 604 to pass through an endotoxin sensor 410' so that the endotoxin level of product fluid can be measured...) See, MPEP 608.01(o). ("While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims.") Support for this new claim can also be found in FIG. 13, which shows endotoxin sensor 410' disposed along a sampling line (element numeral 604 in amended FIG. 13). See above: MPEP 608.04; *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118; and *Autogiro*, 384 F.2d 391, 398, 155 USPQ 697, 703. See also, *In re Wolfensperger*, 133 USPQ 537, 542 (CCPA 1962) ("If the drawing, then, contains the necessary disclosure, it *can* 'form the basis of a valid claim'.").

IV. Restriction Requirement

The Examiner has required restriction pursuant to 36 U.S.C. § 121. The Examiner has distinguished the following inventions: claims 1-26 and 31-53 (Invention I) drawn to a fluid processor; claims 27-30 (Invention II) drawn to methods of sanitizing; claims 54-64

(Invention III) drawn to method of processing; and claims 65-72 (Invention IV) drawn to a compact processor assembly. In response to the restriction requirement, Applicants hereby elect to prosecute claims 1-26 and 31-53 of Invention I. This election is made with traverse for the reasons stated below.

The Examiner states that Invention II and I together with Invention IV are related as process and apparatuses for its practice. The Examiner further states that under MPEP § 806.5(e), these inventions are distinct because the apparatuses could be used to practice another and materially different process, specifically, "a process including the step of sterilization prior to shut down by circulating a disinfectant through the fluid processor." Applicants respectfully disagree.

The apparatuses of Inventions I and IV respectively relate to a fluid processor and a processor assembly suitable for use in a fluid processor, wherein processing a fluid can comprise heating or cooling the fluid. The example given by the Examiner to show that these apparatuses could be used to practice another and materially different process merely adds a step to the processing of a fluid. The Examiner's example still relates to processing a fluid and is not another or materially different process as required by MPEP § 806.5(e). In addition, Applicants point out that claims 27-30 (Invention II) all depend from claim 24 of Invention I (and ultimately depend from claim 1). Also, claims 27-30 (Invention II) all relate to methods for sanitizing the fluid processor recited in claim 24 (Invention I). Further, the methods of sanitizing of Invention II all require manipulating one or more elements of the fluid processor recited in claim 24 (Invention I). For example, claim 27 recites opening the "isolation valve" (of the fluid processor recited in claim 24). Since the methods of sanitizing (Invention II) all relate to the fluid

processor recited in claim 24 (Invention I), Inventions I and II are not distinct with respect to each other and should be combined for restriction purposes.

The Examiner states that Inventions III and I together with IV are related as process and apparatuses for its practice. The Examiner further states that these inventions are distinct under MPEP § 806.05(e) because the apparatuses could be used to practice another and materially different process, specifically, "to purify drinking water or to produce sterile air." Applicants respectfully disagree.

The process of Invention III relates to methods for processing a fluid in a fluid processor, wherein processing the fluid can comprise heating or cooling the fluid. As previously discussed above, the apparatuses of Inventions I and IV respectively relate to a fluid processor and a processor assembly suitable for use in a fluid processor, wherein processing a fluid can comprise heating or cooling the fluid. Clearly, Inventions III, I and IV all relate to the same process – that is, processing a fluid in a fluid processor by heating or cooling. In the Examiner's example, purifying drinking water or producing sterile air using the apparatuses (Invention I and IV) still involves processing water or air in a fluid processor by heating or cooling. Clearly, the Examiner's example is not another or materially different process as required by MPEP § 806.05(e) but actually the same process. In addition, Applicants point out that Inventions I and III are not distinct with respect to each other. Inventions I includes independent claim 1 and Invention III includes independent claim 54. Claims 1 and 54 both relate to processing a fluid in a fluid processor and controlling the pressure and flow rate of the fluid using certain components (e.g., a pressure relief valve). Thus, there is significant overlap between claims 1 and 54 and separate prior art searches are not required. Therefore, restriction is not proper as between Invention I and III.

The Examiner states that Inventions I and IV are related as combination and subcombination. The Examiner further states that that inventions in this relationship are distinct under MPEP § 806.05(c) because the combination as claimed does not require the particulars of the four part block assembly connected by bolts as shown in FIG. 5B and claimed via "means for maximizing heat transfer" as required by the subcombination and the subcombination has separate utility such as for heating or cooling a beverage. Applicants respectfully disagree.

What Examiner describes as a subcombination (i.e., Invention IV) comprises independent claims 65 and 69 and several claims dependent therefrom. Claims 65 and 69 both recite a reactor for converting a process fluid into a product fluid by heating (claim 65) or cooling (claim 69). As the is heated or cooled, a conversion of a process fluid into a product takes place. In the example given by the Examiner, a beverage is merely heated or cooled. However, the beverage itself is not converted into something different as required by claims 65 and 69. Therefore, the subcombination does not have a separate utility as required by MPEP § 806.05(c) and restriction is not proper.

The Examiner states that inventions III and II are related as combination and subcombination. The Examiner further states that these inventions are distinct under MPEP § 806.05(c) because the combination as claimed does not require the particulars of the step of generating steam as required by the subcombinations and the subcombination has separate utility such as in a method for purifying drinking water or producing sterile air. Applicants respectfully disagree.

As discussed previously above, Invention III relates to methods for processing a fluid in a fluid processor, wherein processing the fluid can comprise heating or cooling the fluid. As also previously discussed above, Inventions I and II are not distinct with respect to each other

and should be combined for restriction purposes and further, that Invention I relates to a fluid processor for processing a fluid wherein processing the fluid can comprise heating or cooling the fluid. Finally, Applicants have pointed out above that Inventions III and I both relate to the same process – that is, processing a fluid in a fluid processor by heating or cooling. In the Examiner's example, purifying drinking water or producing sterile air still involves processing water or air in a fluid processor by heating or cooling. Clearly, the subcombination does not have a separate utility as required by MPEP § 806.05(c) and restriction is not proper.

Finally, it is respectfully submitted that the four sets of claims in Inventions I-IV are sufficiently related that a thorough search for the subject matter of any one group would necessarily encompass a search for the subject matter of the remaining group. Thus, the search of the entire application could be performed without serious burden. "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." MPEP § 803.

For the foregoing reasons, the Examiner is respectfully requested to reconsider and withdraw the Restriction Requirement and to examine all claims in this application.

V. Election of Species Requirement

The Examiner has identified the following claims as generic: claims 1-4, 9-12, 16-19, 23, 24, 27, 28, 54 and 59-64. However, Applicants submit that the following claims are also generic: claim 39 and claim 48.

A. Genus and Species

The Examiner has required an election of species for prosecution on the merits. The Examiner has identified the following species:

1. Processors (P): (a) processors that heat the fluid (P1), and (b) processors that cool the fluid (P2). The Examiner states that claims 45, 46, 47, 57, 65-68, 70-72 are directed to species P1 and that claims 39-44, 58, 69 are directed to species P2. However, Applicants submit that claims 25, 26, and 31-38 are also directed to species P1. In addition, Applicants submit that in accordance with the amendment of claim 70 (*supra*), claims 70-72 are directed to species P2.

2. Flow Restrictors (R): (a) R1 in the form of a capillary, and (b) R2 in the form of an adjustable valve. The Examiner states that claims 5, 6, and 25 are directed to species R1 and that claims 7, 8 and 26 are directed to species R2. Applicants respectfully disagree. Applicants submit that there are actually two different genuses of flow restrictors. The first genus is that of "process control flow restrictors" (RA) which relate to the process control system. See, specification at page 15, line 20 *et seq.* and FIG. 3. The second genus is that of "startup flow restrictors" (RB) that relate to the startup loop assembly. See, specification at page 31, line 10 *et seq.* and FIGS. 10A, 10B). It is clear from the specification and drawings that process control flow restrictors (RA) are different from startup flow restrictors (RB)

Process control flow restrictors (RA) include species RA1 and RA2. Species RA1 relates to fixed setting (not "capillaries" as the Examiner states) flow restrictors and corresponds to claims 5 and 6. Species RA2 relates to adjustable setting (not "adjustable valves" as the Examiner states) flow restrictors and corresponds to claims 7 and 8.

Startup flow restrictors RB include species RB1 and RB2. Species RB1 relates to "fixed setting" flow restrictors and corresponds to claim 25. Species RB2 relates to "adjustable setting" flow restrictors and corresponds to claim 26.

3. Heat Exchanger Arrangements ("HE"): (a) HE1 shown in FIG. 5A, 5B -- which the Examiner states as corresponding to claims 32-44, 51, 52, 55, 65-72; (b) HE2 shown in FIG. 5C -- which the Examiner states as corresponding to claims 32, 34-44, 48, 50-52, 55, 65-72; (c) HE3 shown in FIG. 5D -- which the Examiner states as corresponding to claims claim 32-44, 48, 49, 51, 52, 55, 65-72; (d) HE4 shown in FIG. 6A, 6B -- which the Examiner states as corresponding to claims claim 32-44, 51, 52, 53, 55, 65-72; (e) HE5 shown in FIG. 8A-8C -- which the Examiner states as corresponding to claims 32-34, 45, 46, 51, 52, 55; (f) HE6 shown in FIG. 9 -- which the Examiner states as corresponding to claims claim 32-34, 45, 47, 51, 52, 55; and (g) HE7, the shell and tube heat exchanger (not shown in the drawings) -- which the Examiner states as corresponding to claims 31, 56.

Applicants disagree with the Examiner's characterization of claims 34 and 48. With respect to claim 34, Applicants submit that claim 34 corresponds to species HE1-HE4 only and not HE1-HE6 as the Examiner states. This is because claim 34 recites a heater and a reactor nested within the heat exchanger and this arrangement is not disclosed in HE5 and HE6. With respect to claim 48, this claim recites a multiplicity of heat exchangers. Therefore, claim 48 also corresponds to HE4 and not just HE2-HE3 as the Examiner states.

4. Homogenizers (H): (a) H1 shown in FIG. 5B -- which the Examiner states as corresponding to claims 35-38 41, 42, 44, 65-68, 70-72; (b) H2 shown in FIG. 6A -- which the Examiner states as corresponding to claims 35, 38 41, 43, 44, 65-68, 70-72; and (c) H3 shown in

FIG. 7 -- which the Examiner states as corresponding to claims 35, 37, 38 41, 43, 44, 65-68, and 70-72.

Applicants disagree with Examiner's statements regarding species H2. Specifically, Applicants point out that FIG. 6A does not disclose a homogenizer but rather a reactor 60 inserted into the heater 62 to form a "reactor-heater assembly" 66. See, specification at page 25, line 1-18 and FIG. 6A. Therefore, there is no species H2.

Applicants also disagree with Examiner's characterization of claims 37 and 43. Specifically, claims 37 and 43 both relate only to species H1. This is because claims 37 and 43 both recite a temperature homogenizer having a unitary structure produced by casting wherein the reactor is formed as an integral part of the temperature homogenizer. In contrast, species H3 discloses a reactor-heater assembly comprising a reactor in the form of a hollow tube wherein a cartridge type electrical heater is inserted into a heater opening in the reactor. The reactor-heater assemblies, in turn, are placed in cavities in the temperature homogenizer. (*see,* specification at page 25, line 15 *et seq.*) This arrangement in species H3 does not allow the reactor to be formed as an integral part of the temperature homogenizer as disclosed in species H1.

5. Treatment Assemblies (T): (a) T1 shown in FIG. 12A; (b) T2 shown in FIG. 12B; (c) T3 shown in FIG. 12C; (d) T4 shown in FIG. 12D; and (e) T5 shown in FIG. 12F.

6. Shut Down Arrangements (S): (a) S1 shown in FIG. 11B (including the bag 194); and (b) S2 shown in FIG. 11B (including the filter 196).

7. Sensor Arrangements (C): (a) C1 including sensors placed in the product line shown in FIG. 13, which the Examiner states corresponds to claim 20; (b) C2 including

sensors placed in a discharge line (not shown in the drawings), which the Examiner states corresponds to claim 21; and (c) C3 including sensors placed in a divert line not shown in the drawings, which the Examiner states corresponds to claim 22.

Claim 20 has been amended to recite sensors placed along a discharge line rather than a product line. As a result of this amendment, claim 20 now corresponds to species C2. Claim 21 has been amended to recites sensors placed along a divert line. As a result of this amendment, claim 21 now corresponds to species C3. Also, Applicants point out that species C3 is actually disclosed in FIG. 13 which shows a flow sensor (414') and conductivity cell (412') disposed along a divert line (606 in amended FIG. 13). New claim 73 has been added (*supra.*) New claim 73 discloses an endotoxin sensor disposed along a bypass line. Claim 73 is a new species, which Applicants designate as species C4.

B. Applicants' Election of Species

Applicants hereby elect the following species:

Processors: Applicants elect processors that heat the fluid or species **P1**. For the reasons given above, Applicants submit that species P1 corresponds to claims 25, 26, 31-38, 45, 46, 47, 57, and 65-68.

Flow Restrictors: As discussed above, Applicants submit that there are two different genuses of flow restrictors, process control flow restrictors (RA) and startup flow restrictors (RB). For the genus of process control flow restrictors, Applicants elect species RA1 corresponding to claims 5 and 6. For the genus of process control flow restrictors, Applicants

elect species RB1, which corresponds to claim 25. However, if the Examiner does not accept Applicants' arguments (*supra.*), Applicants herby elect species **R1,** which corresponds to claims 5, 6, and 25.

Heat Exchanger Arrangements: Applicants elect species **HE1**, which corresponds to claims 32-44, 51, 52, 55, and 65-72

Homogenizers: Applicants elect species **H3**. For the reasons stated above, Applicants submit that species H3 corresponds to claims 35, 38, 41, 44, 65-68, and 70-72.

Treatment Assemblies: Applicants elect species **T1**, which corresponds to claim 13.

Shut Down Arrangements: Applicants elect species **S2,** which corresponds to claim 30.

Sensor Arrangements: Applicants elect species **C3**. For the reasons stated above, Applicants submit that species C3 corresponds to claims 21 and 22.

Respectfully submitted,

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Glenn F. Ostrager
Reg. No. 29,963
Ostrager Chong Flaherty and
Broitman P.C.
250 Park Avenue, Suite 825
New York, New York 10177-0899
Tel. No.: (212) 681-0600
Customer No. 44702

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to FIG. 13. This sheet, which includes FIG. 13, replaces the original sheet including FIG. 13. In amended FIG. 13, previously omitted element numerals 600, 602, 604 and 606 have been added.

Attachment: Replacement Sheet
Annotated Sheet Showing Changes

ANNOTATED SHEET SHOWING CHANGES

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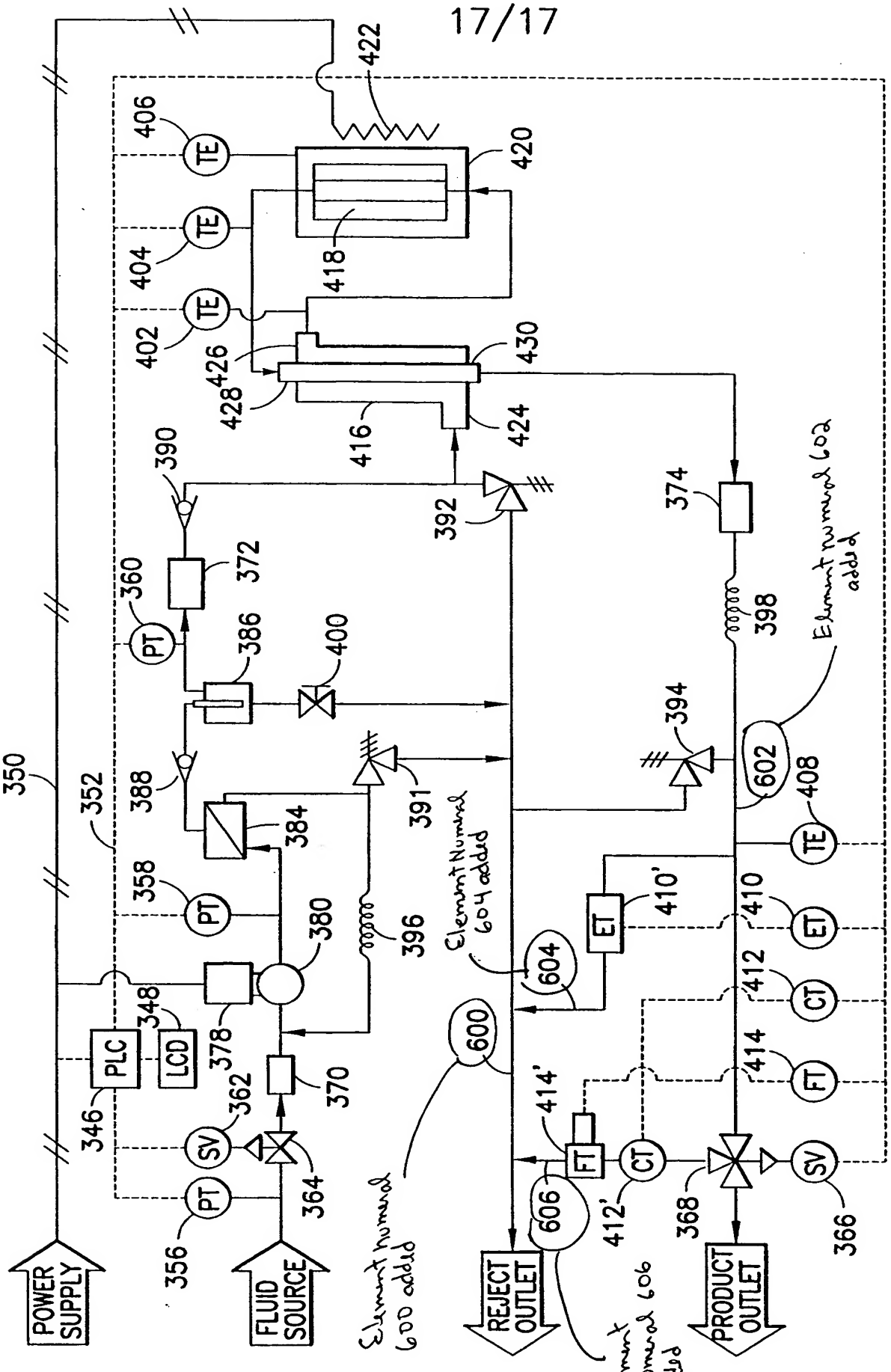

FIG.13